# Trial Description

## Title

**Algorithmic Surveillance of ICU patients to improve personalized management of care**

## Trial Acronym

**ASIC**

## URL of the trial

**http://www.smith.care/ziele/?lang=en**

## Brief Summary in Lay Language

**The patient data of mechanically ventilated ICU (Intensive care unit) patients will be better used to diagnose acute respiratory distress syndrome (ARDS) earlier, more acurate and to initialise a personalised therapy. The intended project aims to the treatment of ICU patients at risk for ARDS.**

## Brief Summary in Scientific Language

**By means of model-based, algorithmic surveillance and continuous monitoring, analysis of patient data of mechanically ventilated ICU patients will be performed. An app-based decision support system will support physicians to diagnose acute respiratory distress syndrome (ARDS) earlier. Through the analysis of large-scale data from patient data management systems (PDMS) and by the application of high performance computing a diagnostic expert advisor system will help to realize future personalised treatment of ICU patients. The intended project aims to enhance timely diagnosis and evidence-based treatment of ICU patients at risk for ARDS. The evaluation will be performed via stepped-wedge-design.**

## Do you plan to share individual participant data with other researchers?

**No**

## Description IPD sharing plan

**[---]***

## Organizational Data

- DRKS-ID: **DRKS00014330**
- Date of Registration in DRKS: **2019/05/24**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EK 102/19 , Ethik-Kommission an der Medizinischen Fakultät der RWTH Aachen**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **J80.01 - [generalization J80: Adult respiratory distress syndrome]**
- ICD10: **J80.02 - [generalization J80: Adult respiratory distress syndrome]**
- ICD10: **J80.03 - [generalization J80: Adult respiratory distress syndrome]**

## Interventions/Observational Groups

- Arm 1: **TAU ("treatment as usual")**
- Arm 2: **By means of model-based, algorithmic surveillance and continuous monitoring, analysis of patient data of mechanically ventilated ICU patients will be performed. An app-based decision support system will support physicians to diagnose acute respiratory distress syndrome (ARDS) earlier. Through the analysis of large-scale data from patient data management systems (PDMS) and by the application of high performance computing a diagnostic expert advisor system will help to realize future personalised treatment of ICU patients. The intended project aims to enhance timely diagnosis and evidence-based treatment of ICU patients at risk for ARDS. The evaluation will be performed via stepped-wedge-design.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***

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Study Type Non-Interventional: **Other**

Allocation: **Other**

Blinding: **[---]***

Who is blinded: **[---]***

- Control: **Other**
- Purpose: **Other**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Co-primary:**
**- Detection rate of ARDS (acute respiratory distress syndrome) and adherence to lung protective ventilation of patients with ARDS**

### Secondary Outcome

**- organ dysfunctions**
**- length of ICU (Intensive Care Unit) stay**
**- days on mechanical ventilation (MV): days off MV**
**- hospital / ICU readmissions**
**- technology (mobile devices) acceptance and usage**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- University Medical Center **Aachen**
- University Medical Center **Leipzig**
- University Medical Center **Jena**
- University Medical Center **Bonn**
- University Medical Center **Hamburg**
- University Medical Center **Halle Saale**
- University Medical Center **Düsseldorf**
- University Medical Center **Rostock**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/07/01**
- Target Sample Size: **6000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

### Additional Inclusion Criteria

**ICU (Intensive Care Unit) patients requiring mechanical ventilation for >24 hours**

### Exclusion criteria

**None**

## Addresses

- **Primary Sponsor**

  **Universitätsklinikum Aachen, AöR**
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- **Contact for Scientific Queries**

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## Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

  **Bundesministerium für Bildung und Forschung Dienstsitz Berlin**
  **Friedrichstraße 130 B**
  **10117 Berlin**
  **Germany**

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **www.bmbf.de**

## Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **[---]***
- Number of Participants in Germany after Recruiting complete: **[---]***
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **[---]***

## Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*